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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,406	10/17/2005	Tasuku Honjo	Q90923	3704

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EXAMINER	
LAM, ANN Y	

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1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,406	HONJO ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-7 and 9-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I claim(s) 1-4, 6, 7, 9, 18 and 19, drawn to a screening method of a substance or a pharmaceutical composition made by selecting a substance with activity by the screening method, and/or administering the composition, classified in class, 435, subclass 4, and class 514, subclass 1.

Group II, claim 5, drawn to a method for treating cardiac disease, classified in class 514, subclass 1.

Group III, claims 10-11, drawn to an apparatus for therapy of cardiac disease, classified in class 210, subclass 638.

Group IV, claims 12-15, drawn to a method for making an animal model for evaluating cardiac disease, classified in class 422, subclass 67.

Group V, claim(s) 16, drawn to a method for treating a cardiac disease, classified in class, 514, subclass 1, and class 435, subclass 7.1.

Group VI, claim 20, drawn to a method for treating dilated cardiomyopahty, classified in class 435, subclass 7.1.

(It is noted that claim 17 will be examined if either claim 16 or claim 20 is elected, as it appears to not pose a burden to examine along with either claim 16 or claim 20.)

(a)

The inventions listed as Groups I, II, IV and V do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack a common special technical feature over the prior art for the following reasons.

The technical feature linking Groups I, II, IV and V appears to be that they all relate to treating a cardiac disease by administering a composition.

However, Salcedo et al., 7,064,189, discloses administering a therapeutic composition to treat ischemic injury such as that caused by myocardial infarction (col. 133, lines 50-59.) Therefore, the technical feature linking the inventions of groups I, II, IV and V does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

More specifically with respect to Group V, this Group includes two different methods: a method for treating dilated cardiomyopathy (claim 16); and a diagnosis method of dilated cardiomyopathy (claim 17). As to the method of claim 16, the technical feature that links claim 16 and Groups II, IV and V, relates to treating a cardiac disease by administering a composition, which as indicated above, does not constitute a special technical feature as it does not define a contribution over the prior art, in view of the Salcedo et al. disclosure. As to the method of claim 17, the technical feature that links claim 17 and Groups I and IV is an anti-cardiac troponin I antibody, which is known in the art as disclosed by Buechler et al., 5,795,725, column 9, lines 52-57. As to claim 17 and Group II (claim 5), there is no technical feature that links claim 17 and Group II (claim 5). (Claim 5 is directed to a method for *treating* cardiac disease comprising administering cardiac *troponin I* protein, a partial protein thereof, or modified protein

thereof, and claim 17 is directed to a *diagnosis* method of dilated cardiomyopathy comprising measuring an amount of anti-cardiac troponin I *autoantibody*. While claims 5 and 17 both relate to a cardiac disease, they are directed to different methods, i.e., a method of *treating* and a method of *diagnosis*, and the steps of the methods do not have any elements that link them together, except perhaps for cardiac troponin I, which in any case is disclosed by Buechler et al., 5,795,725, column 9, lines 52-57.)

The special technical feature of Group I is considered to be a screening method of a substance comprising measuring the *inhibitory activity of the substance, 1) on interaction between anti-cardiac troponin I antibody and cardiac troponin I, or 2) on the effect of anti-cardiac troponin I antibody on a target tissue;* and/or a pharmaceutical composition made by selecting a substance with activity by the screening method; and/or administering such a composition.

The special technical feature of Group II is considered to be administering *cardiac troponin I protein*, a partial protein thereof, or a modified protein thereof.

The special technical feature of Group IV is considered to be administering *anti-cardiac troponin I antibody* and evaluating a cardiac disease.

The special technical feature of Group V is considered to be administering a substance that *inhibits the production of anti-cardiac troponin I autoantibody* for treating dilated cardiomyopathy, or diagnosing dilated cardiomyopathy by measuring an amount of anti-cardiac troponin I autoantibody. (A substance that inhibits the production of anti-cardiac troponin I autoantibody, as claimed in Group V, is not necessarily a substance that will inhibit interaction between anti-cardiac troponin I antibody and cardiac troponin

I, nor will it necessarily inhibit the effect of anti-cardiac troponin I antibody on a target tissue, as claimed in Group I, and vice versa.)

Accordingly, Groups I, II, IV and V are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

(b)

The inventions listed as Groups (I, II, V) and III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack a common special technical feature over the prior art for the following reasons.

The technical feature linking the Groups I and III appears to be that they all relate to a therapeutic material selected by the method of Group I. Group III is directed to an apparatus that contacts plasma and the therapeutic material. Applicant recites in the claims of Group III that the apparatus comprises "....an extracorporeal immunity absorbing apparatus that contacts between separated plasma and the therapeutic base material for cardiac disease according to claim 7". Given one interpretation, the apparatus, does not actually include the therapeutic base material, and only needs to be capable of contacting the therapeutic material *and does not need to actually include the therapeutic material*. In this case, the technical feature linking Groups I and III relates to a material that is capable of being used therapeutically for a cardiac disease and is capable of contacting plasma inside an apparatus.

Halbert, 4,637,880, however disclose that toxic levels of a cardiac drug can be reduced from blood plasma in an extracorporeal system (col. 2, lines 6-14 and col. 5, lines 5-11), and thus Halbert disclose a material that is capable of being used therapeutically for a cardiac disease and is capable of contacting plasma inside an apparatus.

More specifically with respect to Group V, this Group includes two different methods: a method for treating dilated cardiomyopathy (claim 16); and a diagnosis method of dilated cardiomyopathy (claim 17). As to the method of claim 16, the technical feature that links claim 16 and Groups III relates to a material that is capable of being used therapeutically for a cardiac disease and is capable of contacting plasma inside an apparatus, which is disclosed by Halbert, 4,637,880, as indicated above. As to the method of claim 17, there is no technical feature that links claim 17 and Group III, except for maybe cardiac troponin antibody, which in any case is disclosed by Buechler et al., 5,795,725, column 9, lines 52-57.)

Therefore, the technical feature linking the inventions of groups (I, II, V) and III does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be a screening method of a substance comprising measuring the *inhibitory activity of the substance, 1) on interaction between anti-cardiac troponin I antibody and cardiac troponin I, or 2) on the effect of anti-cardiac troponin I antibody on a target tissue;* and/or a pharmaceutical

composition made by selecting a substance with activity by the screening method; and/or administering such a composition.

The special technical feature of Group II is considered to be administering *cardiac troponin I protein*, a partial protein thereof, or a modified protein thereof.

The special technical feature of Group III is considered to be an apparatus that comprises a plasma separating apparatus; an extracorporeal immunity absorbing apparatus that contacts between separated plasma and the therapeutic base material for cardiac disease according to claim 7 (interpreted to be capable of contacting separated plasma and the therapeutic base material for cardiac disease according to claim 7); and a reflux apparatus.

The special technical feature of Group V is considered to be administering a substance that *inhibits the production of anti-cardiac troponin I autoantibody* for treating dilated cardiomyopathy, or diagnosing dilated cardiomyopathy by measuring an amount of anti-cardiac troponin I autoantibody. (A substance that inhibits the production of anti-cardiac troponin I autoantibody, as claimed in Group V, is not necessarily a substance that will inhibit interaction between anti-cardiac troponin I antibody and cardiac troponin I, nor will it necessarily inhibit the effect of anti-cardiac troponin I antibody on a target tissue, as claimed in Group I, and vice versa.)

Accordingly, Groups (I, II, V) and III are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Given another interpretation of the claims of Group III, the apparatus *actually comprises the "therapeutic base material for cardiac disease according to claim 7"*. If

this is actually Applicants' intention, *then the apparatus of Group III will be rejoined with group I*.

(c)

The inventions listed as Groups III and IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack a common special technical feature over the prior art for the following reasons.

The technical feature linking the Groups III and IV appears to be that they all relate to a drug relating to a cardiac disease.

Halbert, 4,637,880, however disclose a cardiac drug (col. 5, lines 5-11). Therefore, the technical feature linking the inventions of groups III and IV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group III is considered to be an apparatus that comprises a plasma separating apparatus; an extracorporeal immunity absorbing apparatus that contacts between separated plasma and the therapeutic base material for cardiac disease according to claim 7 (interpreted to be capable of contacting separated plasma and the therapeutic base material for cardiac disease according to claim 7, or interpreted to mean that the apparatus comprises the therapeutic base material); and a reflux apparatus.

The special technical feature of Group IV is considered to be a method for making an animal model for evaluating cardiac disease, comprising administering anti-cardiac troponin I antibody. (The therapeutic base material for cardiac disease selected by the method of claim 7 does not require that the material be cardiac troponin I antibody, and the apparatus of Group III does not require that the therapeutic base material be cardiac troponin I antibody.)

Accordingly, Groups III and IV are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

(d)

The inventions listed as Groups V and VI do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack a common special technical feature over the prior art for the following reasons.

The technical feature linking the Groups V and VI appears to be that they all relate to treating dilated cardiomyopathy. (The treatments however are different since administering a substance that inhibits the production of anti-cardiac troponin I autoantibody does not require removing anti-cardiac troponin I autoantibody, and vice versa.)

However, Baker et al., 5,534,615, disclose a method for treating cardiomyopathy (col. 60, lines 9-47). Therefore, the technical feature linking the inventions of groups V

and vI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group V is considered to be a method comprising administering a substance that inhibits the production of anti-cardiac troponin I autoantibody.

The special technical feature of Group VI is considered to be a method comprising removing anti-cardiac tropnonin I autoantibody.

Accordingly, Groups V and VI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

(e)

The inventions listed as Groups (I, III and IV) and VI do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack a common special technical feature over the prior art for the following reasons.

The technical feature linking Groups (I, III and IV) and VI appears to be that they relate to anticardiac troponin I antibody, which is known in the art as disclosed by Buechler et al., 5,795,725, column 9, lines 52-57).

Therefore, the technical feature linking the inventions of groups V and VI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be a screening method of a substance comprising measuring the inhibitory activity of the substance, 1) on

interaction between anti-cardiac troponin I antibody and cardiac troponin I, or 2) on the effect of anti-cardiac troponin I antibody on a target tissue; and/or a pharmaceutical composition made by selecting a substance with activity by the screening method; and/or administering such a composition.

The special technical feature of Group III is considered to be an apparatus that comprises a plasma separating apparatus; an extracorporeal immunity absorbing apparatus that contacts between separated plasma and the therapeutic base material for cardiac disease according to claim 7 (interpreted to be capable of contacting separated plasma and the therapeutic base material for cardiac disease according to claim 7); and a reflux apparatus.

The special technical feature of Group IV is considered to be a method for making an animal model for evaluating cardiac disease, comprising administering anti-cardiac troponin I antibody.

The special technical feature of Group VI is considered to be a method comprising removing anti-cardiac tropnonin I autoantibody.

Accordingly, Groups (I, III and IV) and VI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept

(f)

The inventions listed as Groups II and VI do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack a common special technical feature over the prior art for the following reasons.

The technical feature linking Groups II and VI appears to be that they relate to treating cardiac disease, which is known in the art as disclosed by Buechler et al., 5,795,725, column 9, lines 52-57).

Therefore, the technical feature linking the inventions of groups II and VI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group II is considered to be administering cardiac troponin I protein, a partial protein thereof, or a modified protein thereof.

The special technical feature of Group VI is considered to be a method comprising removing anti-cardiac tropnonin I autoantibody.

Accordingly, Groups II and VI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept

Moreover, the search for all the groups would be a serious burden on examiner because the inventions have acquired a separate status in the art in view of their different classification, and thus restriction for examination purposes as indicated is proper.

It is noted that in an interview with Applicants' attorney on March 16, 2007, Examiner would consider examining claims 16 and 20 together but that Examiner would like to take a closer look before making that determination. Upon a cursory search of the prior art, Examiner finds that examining claims 16 and 20 together would pose a serious burden on Examiner since there is a high volume of prior art on the subject matter of

treating dilated cardiomyopathy as well as anti-cardiac troponin I autoantibody. Thus, given the reasons for lack of unity as indicated above as well as the serious burden of searching and considering the prior art for claims 16 and 20, which require very different steps as indicated above, Examiner finds that a requirement for an election of an invention is appropriate.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ANN YEN LAM
PATENT EXAMINER